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IVD regulatory solutions

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Your guide to the **In Vitro Diagnostic Directive**

The purpose of the BSI In Vitro Diagnostic Directive (IVDD), 98/79/EC Guide is to provide useful information to in vitro diagnostic device manufacturers and other interested parties seeking to place products on to the European market. The guide provides an initial understanding of the IVDD setting out the regulatory requirements for obtaining CE marking. Information is also presented on how to determine if you require a Notified Body to assess conformity prior to affixing a CE mark.

If you think you may need a Notified Body, whether your device ranges from simple to complex, BSI's in-house team of experts deliver professional, fast and responsive services with the highest quality and most efficient reviews possible.

In Vitro Diagnostics (IVD) is an essential and fast growing part of the global healthcare system, which add value to patients, medical professionals and the industry as well as enhancing the well-being of the population as a whole.

The aim of the **In Vitro Diagnostic Directive (98/79/EC)**

The In Vitro Diagnostic Directive (IVDD) 98/79/EC was introduced in the later part of 1998 and compliance became mandatory on December 7, 2003. The Directive provides regulatory requirements that facilitate the free trade within the European Economic Area (EEA), which comprises the 28 European Union (EU) member states plus Iceland, Liechtenstein and Norway as members of the European Economic Area (EEA).

The IVDD specifically addresses the safety, quality and performance of In Vitro Diagnostic Medical Devices (IVDs). The aim of the Directive is to ensure that IVDs do not compromise the health and safety of patients, users and third parties and attain the performance levels specified by the manufacturer.

The manufacturer is responsible for ensuring their products comply with the Essential Requirements of the Directive before affixing the CE mark and legally gaining access and free movement within the EEA. For some devices a Notified Body may be required to conduct a conformity assessment before the device can be placed on the European market.

In terms of biology, 'In Vitro' means outside of or away from the body. In Vitro Devices require a specimen that is taken from the body and used for testing, either directly by the device, or in a laboratory.





What is an **In Vitro Medical Device**?

IVDs are medical devices and accessories used to perform tests on samples, such as blood, urine, tissue, effectively any sample which can be taken away from the human body to help detect infection, diagnose a medical condition, prevent disease or monitor drug therapies.

The first step is to determine if the product is an in vitro diagnostic medical device as defined by the Directive. Article 1, point 2b of the In Vitro Diagnostic Device Directive (IVDD) defines an IVD as; any medical device which is a reagent, reagent product, calibrator, control material kit, instrument, apparatus, equipment, system whether used alone or in combination, intended by the

manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state of health or disease, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

Who does the **Directive** apply to?

The Directive applies to all IVDs sold in the EEA regardless of where they are designed and manufactured. If the manufacturer is based outside the EEA they may still be responsible for ensuring a device meets the requirements of the Directive and in addition an authorised representative based in Europe will be required.

The Directive lists "Essential Requirements" to which all IVDs must comply before being placed on the market. These requirements address the design, production, labelling and instructions for use. Not all the Essential Requirements will apply to all devices; the manufacturer determines which are appropriate for their device according to the manufacturer's intended purpose.

The Essential Requirements address the risk of the device including:

- Analytical and diagnostic sensitivity
- Analytical and diagnostic specificity
- Accuracy
- Repeatability
- Reproducibility
- Classification
- Conformity

Classification and the Conformity Assessment Routes

There are a number of ways you can demonstrate conformity with the Directive, these involve a choice of testing and quality assurance modules. The choices available depend on the classification of the device.

The Directive groups IVDs into four categories according to the perceived risk associated with the relative hazard to public health and/or patient treatment by an IVD failing to perform as intended.

The diagram below shows the classification and indicates where a Notified Body is required.

Annex II of the Directive contains an inclusive list of products which require certification by a third party called a Notified Body. Only the devices specifically listed in Annex II require a Notified Body, for example PSA is the only cancer marker in Annex II List B.

IVD Classification		Examples
Annex II List A	Notified Body required Design Dossier Review <i>(Including Compliance to the CTS)</i> Audit of quality management system batches released by the Notified Body	HIV, Hepatitis ABO Blood Grouping
Annex II List B	Notified Body required Audit of technical documentation & quality management system	Rubella, PSA, Self Test for Blood Glucose
Self Test	Notified Body required Review of design & labeling for lay user suitability	Pregnancy, Cholesterol Home Tests
General	No Notified Body required Manufacturer self declares	Tests for Hormones, Cardiac Markers, Hematology and Clinical Chemistry Tests

Additional Requirements

The Directive includes ongoing obligations for the manufacturer with regards to experience gained in the post-production phase, including implementation of any necessary corrective actions. The manufacturer must maintain a 'Vigilance System' and notify the regulatory authorities of any serious incident which could or has put a patient at risk, or requires a product to be systematically recalled. An incident should be reported to the Competent Authority in the country where the incident has occurred.

Manufacturers who do not have a registered place of business in the EU must designate an Authorised Representative to perform certain

obligations. The Authorised Representative will be the first point of contact for Competent Authorities. During a vigilance or compliance case, they may be asked to provide documents to the Competent Authority on behalf of the manufacturer.

Manufacturers with Annex II List A devices are required to have every batch released by the Notified Body, which may often require testing of the product. BSI works with the Paul Ehrlich Institut in Germany to deliver this service, who are world leaders in this field.

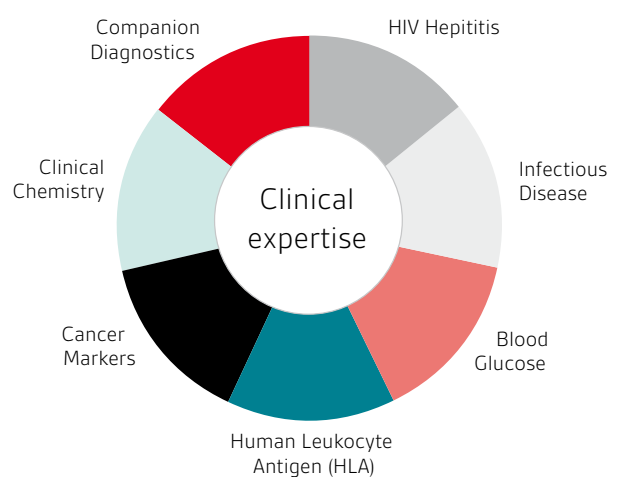
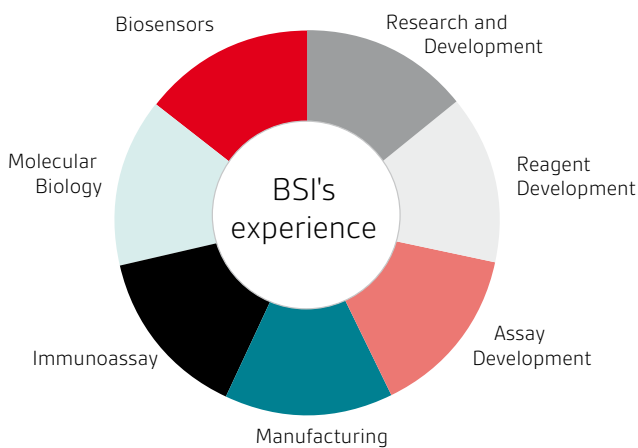
BSI's experience

BSI Healthcare is justifiably proud of its status in the industry as an In Vitro Diagnostic Notified Body. Nowhere is this more clearly seen than in our level of experience and expertise, our large specialist in-house team has 10 technical experts supported by our field based quality assurance assessors.

IVDs are increasingly integrated with other technologies from devices utilizing radio and telecommunications technology to continuous blood glucose meters and companion diagnostics.

BSI's IVD team is integrated with the wider medical device Notified Body so whether you need a simple swab approving or a more complex device using wifi technology we have access to the experts to support you.

Our in-house experts have an average of 13 years IVD experience in...



Three **unique reasons** to make BSI your In Vitro Diagnostics Notified Body

Experience and expertise – The IVD team has a wealth of industrial experience so we understand the challenges you face.

Focus on service – BSI provides all CE customers with a Scheme Manager, so you have a single point of contact for all your queries.

Market Access – BSI provides a range of service level agreements increasing the predictability of the regulatory process and providing premium services to enhance your speed to market.



A resource for excellence

Talk to BSI

- We have over 3,000 members of staff
- 76 BSI offices around the world
- 80,000 clients operating in 182 countries
- Together our clients account for 77% of the FTSE 100, 45% of the Fortune 500 and 65% of the Nikkei listed companies
- We are one of the world's largest independent certification bodies for management systems, with over 121,000 registered sites across the globe.

Additional services

Medical device e-update service – Keep updated on what's happening in the industry and changes in regulatory and quality requirements. You can take advantage of this free service by signing up at our website.

Informational webinars – We offer a wide variety of interactive multimedia presentations allowing convenient participation via a web-based interface.

Guidance documents – Our online Guidance Documents provide assistance in understanding the requirements of the medical devices directives.

Standards – BSI British Standards delivers leading-edge best practice solutions through the development and publication of more than 34,000 standards and related products.

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